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PATENT  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Anthony P. Adamis, et al.      Art Unit: 1632  
Serial No.: 09/478,099      Examiner: A. Baker  
Filed: January 5, 2000  
Title: TARGETED TRANSSCLERAL CONTROLLED RELEASE DRUG  
DELIVERY TO THE RETINA AND CHOROID

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REPLY

In response to the Office Action dated August 15, 2001, in which the Examiner rejects Claims 1-18 under 35 U.S.C. 112 for lack of enablement, Applicants respectfully request that this rejection be withdrawn, in view of the following Remarks.

REMARKS

The present invention provides a method for the targeted delivery of therapeutic nucleic acid molecule across the sclera of the eye of a mammal for a therapeutic purpose, e.g., the treatment of an eye disease such as macular degeneration. The claims have been rejected under 35 U.S.C. §112, for lack of enablement, primarily on the ground that the claims are directed to gene therapy, which is unpredictable, i.e., "not routinely successful." The Examiner has not questioned whether the specification adequately enables the delivery of a nucleic acid molecule into the eye across the sclera; the only issue is whether, once delivered, nucleic acids would be therapeutically effective.